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EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/29/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,826

Applicant(s)

CURRIE ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-12, 16-17, 20, 23-35, 39-40, 43-44, 59-61, 63-72, 74, 76-77, 80, 82, 86, 92-94, and 105-111 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,233,471 to Berner et al. Berner et al. discloses a method and apparatus for obtaining a sample iontophoretically which includes a collection reservoir and a biosensor which can employ physical, chemical, electrochemical, spectrophotometric, polarimetric, colorimetric, or radiometric measurements. (column 13, lines 25-61 of Berner et al.). Berner et al. teaches the use of electronics such as a microprocessor, memory, and a display for operating the sampling system. (column 6, lines 40-50 of Berner et al.). Berner et al. teaches a procedure for correcting the measurement data by measuring the temperature of the biological system. (column 22, line 64 to column 24, line 3 of Berner et al.). Berner et al. teaches the transmission of output data to a pump or insulin delivery system. (column 34, lines 36-40 of Berner et al.). In regard to claims 4, 11, 64, and 71, means for enhancing permeability of the skin are employed.

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(column 4, lines 7-11 of Berner et al.). In regard to claims 12 and 35, several collection reservoirs can be employed. (column 14, lines 26-34 of Berner et al.). In regard to claims 5-10, 29-34, 65-70, 76-77, 105, and 108, Berner et al. discloses that the sampling techniques that can be employed include iontophoresis, sonophoresis, suction, electroporation, thermal poration, passive diffusion, lances subcutaneous implants, and laser devices. (column 6, lines 8-25 of Berner et al.). In regard to claims 16-17 and 39-40, the collection reservoir can be a receptacle containing a material which is ionically conductive (water with ions), a sponge-like material, hydrophilic polymer, or a hydrogel. (column 6, lines 26-39 of Berner et al.). In regard to claims 20, 43, and 94, the biosensor can include a reactive surface. (column 8, lines 17-60 of Berner et al.). In regard to claims 23-24 and 109-110, the device compensates for the biological system's temperature or the temperature fluctuations in the biosensor element caused by environmental conditions. (column 22, line 64 to column 23, line 7 of Berner et al.). In regard to claim 93, Berner et al. teaches that the sampler includes materials that are substantially impermeable to the analyte to be detected such as glucose. (column 9, lines 50-52 of Berner et al.). In regard to claims 106-107, Berner et al. teaches that the analytes that can be analyzed include: any specific substance or component that one is desirous of detecting and/or measuring in a chemical, physical, enzymatic, or optical analysis, amino acids, enzyme substrates or products indicating a disease state or condition, other markers of disease states or conditions, drugs of abuse, therapeutic and/or pharmacologic agents, electrolytes, physiological analytes of interest, glucose urate/uric acid, carbonate, calcium, potassium, sodium, chloride,

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bicarbonate, glucose, urea, lactate/lactic acid, hydroxybutyrate, cholesterol, triglycerides, creatine, creatinine, insulin, hematocrit, hemoglobin, blood gases, lipids, heavy metals, and the like. (column 10, lines 39-57 of Berner et al.).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 13, 15, 36, 38, 62, 83, 85, 95-104, 112, and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claims 1, 59, 82, 94, and 105 in view of U.S. Patent 5,176,881 to Sepaniak et al. Berner et al. does not teach that the detector system comprises an optical detection system comprised of light sources effective to excite fluorophores. Berner et al. teaches that the sensing device can employ physical, chemical, electrochemical, radiometric, spectrophotometric, polarimetric, colorimetric, or like measurement techniques. (column 13, lines 25-41 of Berner et al.). Sepaniak et al. teaches a sensor used in the analysis of determining the presence and concentration of an analyte using fluorescence. (column 1, line 60 to column 2, line 9 of Sepaniak et al.). Such a sensor falls within the group of sensors suggested by Berner et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Berner et al. to include the biosensor of Sepaniak et al. since Berner et al.

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teaches other measurement techniques can be used and Sepaniak et al. teaches one such measurement technique. In regard to claims 15, 38, 85, and 113, a laser is used. (column 3, lines 44-62 of Sepaniak et al.).

5. Claims 14, 37, 84, and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. in view of U.S. Patent 5,176,881 to Sepaniak et al. as applied to claims 13, 36, 83, and 112, and further in view of U.S. Patent 6,124,597 to Shehada et al. The combination does not teach the use of an LED as the light source. Shehada et al. teaches that in fluorescence detection, lasers and LEDs are suitable substitutes for each other which implies that they are functionally equivalent. (column 15, line 59 to column 16, line 7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute LEDs for the laser in the combination since they are functionally equivalent and Shehada et al. teaches that they are suitable substitutes.

6. Claims 19, 21-22, 42, 87-89, and 96-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claims 1, 16, 26, and 94, and further in view of U.S. Patent 5,458,140 to Eppstein et al. Berner et al. does not teach an adhesive on the sampler for adhering to the skin of a subject. Berner et al. teaches the use of straps to attach the sampler to the body. Eppstein et al. teaches that a strap and adhesive are suitable substitutes for each other for attaching a sampling device on the skin which implies that they are functionally equivalent. (column

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17, lines 19-26 of Eppstein et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute an adhesive for the straps to since they are functionally equivalent and Eppstein et al. teaches that they are suitable substitutes for each other. The combination discloses a method and apparatus for obtaining a sample iontophoretically which includes a collection reservoir and a biosensor. The biosensor can employ physical, chemical, electrochemical, spectrophotometric, polarimetric, colorimetric, or radiometric measurements. (column 13, lines 25-61 of Berner et al.). Berner et al. teaches the use of electronics such as a microprocessor, memory, and a display for operating the sampling system. (column 6, lines 40-50 of Berner et al.). Berner et al. teaches the correction of the measurement data by measuring the temperature of the biological system. (column 22, line 64 to column 24, line 3 of Berner et al.). Berner et al. teaches transmitting output data to a pump or insulin delivery system. (column 34, lines 36-40 of Berner et al.). In regard to claims 21-22, Berner et al. does not teach the use a pump for pumping the fluid which promotes the flow of the analyte to the sampler. Berner et al. teaches that the following sampling techniques can be used: iontophoresis, sonophoresis, suction, electroporation, thermal poration, passive diffusion, lances or cannulas, subcutaneous implants or insertions, and laser devices. Eppstein et al. suggests sampling techniques such as needle puncture, hydraulic jet, laser, and electroporation. (column 5, lines 13-20 of Eppstein et al.). This suggests that hydraulic jet sampling is a suitable substitution for electroporation, needle punctures, and lasers which implies that they are functionally equivalent. Therefore, it would have been obvious to one having ordinary skill in the art

at the time the invention was made to substitute a hydraulic jet sampling method for electroporation, laser sampling, or needle punctures as suggested by Berner et al. since they are functionally equivalent and Eppstein et al. suggests that they are suitable substitutions for each other. In regard to claims 96-100, Berner et al. does not teach the use of the detector system comprises an optical detection system comprised of light sources effective to excite fluorophores. Berner et al. teaches that the sensing device can employ physical, chemical, electrochemical, spectrophotometric, polarimetric, colorimetric, radiometric, or like measurement techniques. (column 13, lines 25-41 of Berner et al.). Eppstein et al. teaches a sensor of the analysis of the presence and concentration of an analyte which detects fluorescence. (column 17, lines 1-18 of Eppstein et al.). Such a sensor falls within the group of sensors suggested by Berner et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Berner et al. to include the biosensor of Eppstein et al. since Berner et al. teaches other measurement techniques can be used and Eppstein et al. teaches one such sensor. The combination teaches the use lectins for binding to glucose. (column 17, lines 1-18 of Eppstein et al.).

7. Claims 45-53 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claim 26, and further in view of U.S. Patent 6,393,318 to Conn et al. Berner et al. does not teach a silicon body. Berner et al. teaches that the sampler includes materials that are substantially impermeable to the analyte to be detected such as glucose. (column 9, lines 50-52 of

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Berner et al.). Conn et al. teaches that silicon elastomers have this kind of property. (column 23, lines 3-31 of Conn et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use silicon for the sampler since Berner et al. teaches that the material should substantially impermeable to glucose and Conn et al. teaches such a material. In regard to claim 46, means for enhancing permeability of the skin is employed. (column 4, lines 7-11 of Berner et al.). In regard to claims 47-53, Berner et al. discloses that the sampling techniques that can be employed include iontophoresis, sonophoresis, suction, electroporation, thermal poration, passive diffusion, lances subcutaneous implants, and laser devices. (column 6, lines 8-25 of Berner et al.).

8. Claims 54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. in view of U.S. Patent 6,393,318 to Conn et al. as applied to claim 46, and further in view of U.S. Patent 5,176,881 to Sepaniak et al. The combination does not teach that the detector system comprises an optical detection system comprised of light sources effective to excite fluorophores. Berner et al. teaches that the sensing device can employ physical, chemical, electrochemical, spectrophotometric, polarimetric, colorimetric, radiometric, or like measurement techniques. (column 13, lines 25-41 of Berner et al.). Sepaniak et al. teaches a sensor used in the analysis to determine the presence and concentration of an analyte using fluorescence. (column 1, line 60 to column 2, line 9 of Sepaniak et al.). Such a sensor falls within the group of sensors suggested by Berner et al. Therefore, it would have

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been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include the biosensor of Sepaniak et al. since Berner et al. teaches other measurement techniques can be used and Sepaniak et al. teaches one such sensor. In regard to claims 56, a laser is used. (column 3, lines 44-62 of Sepaniak et al.).

9. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. in view of U.S. Patent 6,393,318 to Conn et al. in view of U.S. Patent 5,176,881 to Sepaniak et al. as applied to claim 54, and further in view of U.S. Patent 6,124,597 to Shehada et al. The combination does not teach the use of an LED as the light source. Shehada et al. teaches that in fluorescence detection, lasers and LEDs are suitable substitutes for each other which implies that they are functionally equivalent. (column 15, line 59 to column 16, line 7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute LEDs for the laser in the combination since Shehada et al. teaches that they are suitable substitutes for each other.

10. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. in view of U.S. Patent 6,393,318 to Conn et al. as applied to claim 46, and further in view of U.S. Patent 5,458,140 to Eppstein et al. The combination does not teach the use a pump for pumping the fluid which promotes the flow of the analyte to the sampler. Berner et al. teaches that the following sampling

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techniques can be used: iontophoresis, sonophoresis, suction, electroporation, thermal poration, passive diffusion, lances or cannulas, subcutaneous implants or insertions, and laser devices. Eppstein et al. suggests sampling techniques such as needle puncture, hydraulic jet, laser, and electroporation. (column 5, lines 13-20 of Eppstein et al.). This suggests that hydraulic jet sampling is a suitable substitution for electroporation, needle punctures, and lasers which implies that they are functionally equivalent. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a hydraulic jet sampling method for electroporation, laser sampling, or needle punctures as suggested by Berner et al. since they are functionally equivalent and Eppstein et al. suggests that they are suitable substitutions for each other.

11. Claims 73 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claim 72. Berner et al. does not explicitly teach the use of serpentine capillary channels. Berner et al. teaches that the collection reservoir can include tubes, vial, capillary collection devices, cannulas, and miniaturized etched, ablated, or molded flow paths. (column 6, lines 26-39 of Berner et al.). With such a selection of possible components, Berner et al. is implying that the type of collection device and the shape of the flow path depends upon many considerations such as manufacturing cost, size of the components, and preferred configuration of the sensor. This provides a clear suggestion that the collection reservoir can be modified and that the determination of the most appropriate collection

reservoir by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art.

12. Claims 18, 41, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claims 16, 39, and 72, and further in view of U.S. Patent 4,526,176 to Bremer et al. Berner et al. does not teach the use of a seal for retaining the fluid in the reservoir prior to sampling analytes. Berner et al. teaches that the collection reservoir can be a receptacle containing a material which is ionically conductive (water with ions), a sponge-like material, hydrophilic polymer, or a hydrogel. (column 6, lines 26-39 of Berner et al.). It is well known in the art that a breakable seal is used to prevent escape of fluid such as water or hydrogel prior to use. (column 6, lines 11-15 of Bremer et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Berner et al. to include a breakable seal as disclosed by Bremer et al. since seals are used to prevent escape of the fluids prior to use.

13. Claims 78-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claims 76, and further in view of U.S. Patent 4,526,176 to Bremer et al., and further in view of U.S. Patent 6,464,687 to Ishikawa et al. Berner et al. does not teach the use of a seal for retaining the fluid in the reservoir prior to sampling analytes. Berner et al. teaches that the collection reservoir can be a receptacle containing a material which is ionically conductive (water with ions),

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a sponge-like material, hydrophilic polymer, or a hydrogel. (column 6, lines 26-39 of Berner et al.). It is well known in the art that a breakable seal is used to prevent escape of fluid such as water or hydrogel prior to use. (column 6, lines 11-15 of Bremer et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Berner et al. to include a breakable seal as disclosed by Bremer et al. since seals are used to prevent escape of the fluids prior to use. The combination does not teach a method of breaking the seal. Ishikawa et al. teaches the use of a heater to rupture a seal. (column 7, lines 58-62 of Ishikawa et al.). Such a method would fulfill the requirements of rupturing the seal as required by the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include a heater for rupturing the seal as disclosed by Ishikawa et al. since a method of rupturing the seal is required and Ishikawa et al. teaches one such method.

14. Claims 90-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. and further in view of U.S. Patent 5,458,140 to Eppstein et al. as applied to claim 87-89, and further in view of U.S. Patent 5,330,527 to Montecalvo et al. The combination does not teach that the adhesive serves to prevent loss of the physiological compatible fluid or that the adhesive is water impermeable. The combination teaches the use of adhesive as a form of attachment and the use of a hydrogel as a collection reservoir. Montecalvo et al. teaches that adhesives can be used to attach a hydrogel matrix to a patient that protects the hydrogel from the external

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environment. (column 3, lines 34-38 of Montecalvo et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include the use of an adhesive that is water impermeable for sealing the sensor to the patient since such an adhesive protects the hydrogel from the external environment.

Response to Arguments

15. Applicant's arguments filed 10/24/2003 have been fully considered but they are not persuasive. In regard to claims 1, 72, 87, and 92, Berner et al. teaches a sampler and at least one detector system in the form of a sensing device. The Applicant contends that Berner et al. does not contemplate other data obtained from the subject that relates to the condition of the subject, relating the other data to the input information, and displaying the output information. The Examiner respectfully disagrees because Berner et al. teaches a procedure for correcting the measurement data by measuring the temperature of the biological system. (column 22, line 64 to column 24, line 3 of Berner et al.). This procedure is relating the input data (the analyte measurement) to other data (the temperature data). A display outputs the result of the readings by using this procedure. (column 19, lines 12-20 of Berner et al.). The Applicant next contends that Berner et al. does not teach transmitting the information to another system and controlling the operation of the at least one sampler and at least one detector. The Examiner respectfully disagrees because the output data includes commands that are transmitted to another system, i.e., an insulin delivery system.

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(column 34, lines 36-40 of Berner et al.). Berner et al. also teaches suitable electronics such as a microprocessor, memory, display, and power sources for operating the sampling system (column 6, lines 40-43 of Berner et al.) and suitable electronics for controlling the operation of the sensor including receiving, storing, and displaying data (column 19, lines 12-20 of Berner et al.). In regard to claim 26, the Applicant contends that column 15 of Berner et al. clearly reveals there is no teaching or suggestion of assembling a microfabricated device with all the functionality of the device claimed, including the transmitter receiver for transmitting data related to the analyte detected. The Examiner respectfully disagrees because of the teachings found in column 6, line 60 to column 6, line 50 of Berner et al. Berner et al. teaches a device that includes a reservoir as a sampling unit, a sensing means as the detector system, and a microprocessor means in operative communication with the sampling means and the sensing means as a transmitter/receiver. In regard to the Applicant's Argument that Berner et al. does not teach ablation, the Examiner respectfully disagrees because Berner et al. does teach laser ablation in column 6, lines 8-25 of Berner et al.

In regard to the Applicant's Arguments related to the Berner/Sepaniak combination, the Examiner is not persuaded. As to the arguments that the teachings of Sepaniak do not overcome the supposed deficiencies of Berner et al., the rejection of the claims in view of the Berner/Sepaniak combination are maintained because the rejections of the claims in view of Berner are deemed proper due to the reasons stated above. In regard to the Applicant's argument that it is not apparent to them how Sepaniak could be modified to be implemented in a system such as that of Berner, the

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test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). From the teachings of Berner and Sepaniak et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Berner et al. to include the biosensor of Sepaniak et al. since Berner et al. teaches other measurement techniques can be used and Sepaniak et al. teaches one such measurement technique.

As to the arguments that the teachings of Shehada do not overcome the supposed deficiencies of Berner or Sepaniak, the rejection of the claims in view of the Berner/Sepaniak/Shehada combination are maintained because the rejections of the claims in view of Berner and Sepaniak are deemed proper due to the reasons stated above.

As to the arguments that the teachings of Eppstein do not overcome the supposed deficiencies of Berner, the rejection of the claims in view of the Berner/Eppstein combination are maintained because the rejections of the claims in view of Berner are deemed proper due to the reasons stated above. In regard to the Applicant's argument that it is not apparent to them how Eppstein could be modified to be implemented in a system such as that of Berner, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the

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structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). From the teachings of Berner and Eppstein et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute an adhesive for the straps ~~to~~ since they are functionally equivalent and Eppstein et al. teaches that they are suitable substitutes for each other. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a hydraulic jet sampling method for electroporation, laser sampling, or needle punctures as suggested by Berner et al. since they are functionally equivalent and Eppstein et al. suggests that they are suitable substitutions for each other. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Berner et al. to include the biosensor of Eppstein et al. since Berner et al. teaches other measurement techniques can be used and Eppstein et al. teaches one such sensor.

As to the arguments that the teachings of Conn do not overcome the supposed deficiencies of Berner, the rejection of the claims in view of the Berner/Conn combination are maintained because the rejections of the claims in view of Berner are deemed proper due to the reasons stated above.

In response to applicant's argument that the Berner/Bremer combination fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the seal is semi- and selectively permeable) are not recited in the

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rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). From the teachings of Berner and Bremer, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Berner et al. to include a breakable seal as disclosed by Bremer et al. since seals are used to prevent escape of the fluids prior to use.

In response to applicant's argument that the use of the Ishikawa reference is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The use of Ishikawa reference teaches a method of rupturing a seal that is required by the combination and one with ordinary skill in the art would search in the medical arts to find

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a solution to the problem presented by the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include a heater for rupturing the seal as disclosed by Ishikawa et al. since a method of rupturing the seal is required and Ishikawa et al. teaches one such method.

In response to applicant's argument that the use of the Montecalvo is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The use of Montecalvo reference teaches an adhesive that is required by the combination and one with ordinary skill in the art would search in the medical arts to find a solution to the problem presented by the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include the use of an adhesive that is water impermeable for sealing the sensor to the patient since such an adhesive protects the hydrogel from the external environment.

Finally, in response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Matthew Kremer
Assistant Examiner
Art Unit 3736



ERIC F. WINAKUR
PRIMARY EXAMINER